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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

K140803

JUN 26 2014

510(k) Summary

April 9, 2014

Submitter of 510(k):

Company name:	Nucletron BV
Registration number:	611894
Address:	Waardgelder 1, 3905 TH Veenendaal, The Netherlands
Phone:	+31 318 557 133
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Correspondent:	Rudolf Vos

New Device Name:

Trade/Proprietary Name:	Luneray
Common/Usual Name:	Interstitial brachytherapy applicator for remote-afterloading
Classification Name:	Remote controlled radionuclide applicator system accessory
Classification:	21CFR892.5700, Class II
Product code:	JAQ

Legally Marketed Device(s)
Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	Comfort Catheter System	K032372
Nucletron BV	NAG brachyflex	K953946

Description:
Luneray is a pre-assembled, sterile needle-catheter combination for interstitial brachytherapy treatments. The needle is inserted into the tissue and pulls the catheter through the tissue. After insertion the needle is removed from the catheter by cutting it off the catheter.

Radiation treatment planning can be based on X-ray and CT images. X-ray markers shall be used during the imaging procedure, to enable catheter reconstruction in the planning software.

The applicator is connected to a Nucletron brachytherapy afterloader for radiation treatment.

Indications for use:
Luneray is intended for interstitial brachytherapy of soft tissue that allows the insertion of this flexible applicator, e.g.:

- Abdominal structures / organs (e.g. urinary bladder)
- Head and neck (e.g. ear, lip, nose, tongue, oral mucosa)
- Skin (e.g. keloids)
- Soft tissue sarcoma

Luneray enables minimally invasive procedures to be performed both manually and laparoscopically.

The indications for use of Luneray are more specific than the indications for use of the predicate devices. More specificity is added to the tissue type and insertion techniques are specifically mentioned. These modifications do not constitute a new intended use. Submitted validation and clinical literature data demonstrates that the device is as safe and effective as the predicate and support addition of specific indications in this submission.

Summary of technological considerations:
Luneray and the predicate devices provide an unobstructed, closed path for the radioactive source. The devices are used in the hospital by trained professionals. With all devices, imaging for treatment planning possible with X-ray, CT, and MR. All devices are connected to remote afterloader systems.

The differences between Luneray and the predicate devices are related to differences in design and handling of the device. With Luneray, needles and catheters are pre-assembled. With the predicates, needles and catheters are separate components. The predicate devices are handled manually; Luneray can also be handled with laparoscopic tools.

Luneray is delivered sterile. The predicate devices are delivered unsterile (K953946) or some components are delivered sterile (K032372).

The differences do not affect the similarity in principal technology, function and operational characteristics of the devices. As a result, it is determined that the Luneray interstitial brachytherapy applicator is substantially equivalent to the legally marketed predicate devices.

Summary of testing:
Luneray has been tested to meet the product requirements, requirements from (safety) standards and clinical expectations. Verification tests cover Sterilization, Shelf Life, Biocompatibility, Functional verification testing and testing to Standards.

Performance testing was performed at a hospital site, under clinical conditions and with the involvement of clinical personnel but excluding the delivery of treatment of patients. Experienced users reviewed the device design and executed validation tests.

The results of the testing provided in this submission adequately demonstrate that the interstitial brachytherapy applicator Luneray performs as defined in the requirements, in accordance with the recognized standards, meets clinical expectations and is safe and effective for clinical use.

Conclusion:
Nucletron considers the Luneray interstitial brachytherapy applicator to be substantially equivalent to legally marketed predicate device through the data and information presented. No safety or effectiveness issues were identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

NUCLETRON B.V.
RUDOLF VOS
QA/RA ENGINEER
WAARDGELDER 1
VEENENDAAL 3905 TH
THE NETHERLANDS

June 26, 2014

Re: K140803
Trade/Device Name: Luneray:catheter 6f 50cm. Needle 37mm R30mm/47mm R45mm/57mm R60mm/67mm R75 Mm
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: March 27, 2014
Received: March 31, 2014

Dear Mr. Vos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140803

Device Name: Luneray

Indications for Use:

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- Abdominal structures / organs (e.g. urinary bladder)
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- Soft tissue sarcoma

Luneray enables minimally invasive procedures to be performed both manually and laparoscopically.

Prescription Use ___X___ (Part 21 CFR 801 subpart D) AND/OR Over-The-Counter Use_____ (Part 21 CFR 801 subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Michael D. O'Hara